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PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GARY K. MICHELSON

Appeal 2009-009897
Application 08/354,450
Technology Center 3700

Decided: December 9, 2009

Before JENNIFER D. BAHR, LINDA E. HORNER, and
FRED A. SILVERBERG, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*

DECISION ON APPEAL

STATEMENT OF THE CASE

Gary K. Michelson (Appellant) seeks our review under 35 U.S.C. § 134 of the Examiner's decision rejecting claims 29-300. We have jurisdiction under 35 U.S.C. § 6(b) (2002).

SUMMARY OF DECISION

We AFFIRM-IN-PART.

THE INVENTION

Appellant's claimed invention is to a rivet and method for holding pieces of tissue together. Claim 29, reproduced below (paragraphing added), is representative of the subject matter on appeal.

29. A tissue rivet for holding pieces of tissue together and to prevent movement of said rivet in the tissue, said rivet being made of a bioabsorbable material, said rivet comprising
- a shaft having a leading end, a trailing end opposite said leading end, and a mid-longitudinal axis therebetween,
 - said shaft having
 - a maximum cross-sectional dimension transverse to the mid-longitudinal axis,
 - a truncated conical penetration head at said leading end, and
 - a flexible member at said trailing end,
 - said flexible member having a top, a bottom opposite said top, and a dimension larger than the maximum cross-sectional dimension of said shaft,

said flexible member adapted to deform so as to conform to the surface of the tissue in which said rivet is inserted,

said flexible member being at least in part curved when said flexible member is in contact with the tissue,

said shaft having a plurality of flexible projections extending radially from said shaft,

said flexible projections being separate and spaced apart from one another,

at least one of said flexible projections capable of flexing toward said shaft when being inserted in the tissue.

THE EVIDENCE

The Examiner relies upon the following evidence:

| | | |
|----------|--------------|---------------|
| Simons | US 4,338,835 | Jul. 13, 1982 |
| Paravano | US 4,422,276 | Dec. 27, 1983 |
| Duncan | US 4,548,202 | Oct. 22, 1985 |
| Chisholm | US 4,728,238 | Mar. 1, 1988 |
| Bays | US 4,976,715 | Dec. 11, 1990 |
| Warren | US 5,261,914 | Nov. 16, 1993 |

THE OBJECTIONS AND REJECTIONS

Appellant seeks review of the following objections and rejections:

1. The Examiner objected to an amendment filed January 7, 2004 under 35 U.S.C. § 132 for introducing new matter.
2. The Examiner objected to the Specification under 35 U.S.C. § 112, first paragraph, as not providing support for the invention as is now claimed.

3. The Examiner rejected claims 29-175, 183-185, 211-241, 245-247, 274, 275, 284, 285, and 293-300 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.
4. The Examiner rejected claims 29-175, 183-185, 211-241, 245-247, 274, 275, 284, 285, and 293-300 under 35 U.S.C. § 112, second paragraph, as being indefinite.
5. The Examiner rejected claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, and 300 under 35 U.S.C. § 103(a) as being unpatentable over Warren.
6. The Examiner rejected claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, and 256-300 under 35 U.S.C. § 103(a) as being unpatentable over Bays and Warren.
7. The Examiner rejected claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, and 251-258 under 35 U.S.C. § 103(a) as being unpatentable over either Warren or Bays and Warren, and further in view of either Duncan, or Chisholm, or Paravano.
8. The Examiner rejected claims 87, 88, 131, and 132 under 35 U.S.C. § 103(a) as being unpatentable over either Warren or Bays and Warren, and further in view of Simons.

ISSUES

New Matter and Written Description

The Examiner's rejection under 35 U.S.C. § 112, first paragraph, for failure to meet the written description requirement is related to the new matter objection to Appellant's January 7, 2004 amendment. In particular, the Examiner objected to under 35 U.S.C. § 132, and rejected under 35 U.S.C. § 112, first paragraph, certain claim language reciting features and characteristics of the flexible member that were introduced by amendment on the ground that this claim language is not supported by the original disclosure. Ans. 4-9.¹

Ordinarily an objection is reviewable by petition under 37 C.F.R. § 1.181, and a rejection is appealable to the Board of Patent Appeals and Interferences. When the issue of new matter presented is the subject of both an objection and a rejection, the issue is appealable. Manual of Patent Examining Procedure (MPEP) § 2163.06, II. Review of New Matter Objections And/Or Rejections (8th ed., Rev. 8, July 2008). *See also* MPEP § 608.04(c) (8th ed., Rev. 8, July 2008) ("where the alleged new matter is introduced into or affects the claims, thus necessitating their rejection on this ground, the question becomes an appealable one, and should not be considered on petition even though that new matter has been introduced into the specification also."). Because the objection to the claim amendment and the written description rejection turn on the same issue of whether the

¹ All references to "Ans." refer to the Examiner's Answer of February 19, 2008.

amended claim language is adequately supported by the original disclosure, we will analyze the objection and rejection collectively.²

The issues presented by this appeal include:

Has Appellant shown the Examiner erred in determining that the original disclosure fails to provide adequate written description of the claimed features and characteristics of the flexible member?

Indefiniteness

The Examiner's rejection of the claims under 35 U.S.C. § 112, second paragraph, is similarly based on the ground that the amended claim language is not supported by the original disclosure. Ans. 10 (stating that the metes and bounds of the claims are not clear because the claim language that formed the basis for the written description rejection has no clear support in the specification as originally filed.).

² The Examiner also objected to the Specification under 35 U.S.C. § 112, first paragraph, because it does not provide support for the invention as is now claimed. Ans. 7. To the extent that this objection turns on the same issues as the new matter objection and the written description rejection of the claims, our decision with respect to the new matter objection and written description rejection likewise is dispositive as to the corresponding § 112, first paragraph, objection. Because we address the new matter/written description issue in our analysis of the new matter objection and written description rejection *infra*, the Examiner should consider taking appropriate action with respect to the § 112 objection commensurate with our decision.

Appellant argues that the indefiniteness rejection is improper because the rationale supporting the rejection relates to issues of inadequate written support and not to indefiniteness. First Reply Br. 9.³

The issues presented by this appeal include:

Has Appellant shown the Examiner erred in determining that the claims are indefinite based on the rationale that they contain language not supported by the original disclosure?

Obviousness

Rejection based on Warren

The Examiner found that Warren discloses all of the elements of the rejected claims except that Warren does not disclose dimensions or sizes of the different parts and how the fastener flexes during use. Ans. 13. The Examiner then determined that because Warren teaches that the specific dimensions and sizes of the different parts of the rivet can be modified to fit a particular intended use, it would have been obvious to change the dimensions of the rivet, e.g., to reduce the size of the head, to find the optimum characteristics for a particular intended use. *Id.* The Examiner added that it would have been obvious to change the dimensions of the flexible member to reduce the amount of material used or the size to make it less obtrusive. Ans. 14.

³ Our reference to “First Reply Br.” refers to Appellant’s Reply Brief filed on September 1, 2005.

Appellant argues that the Examiner erred by failing to take into account the context in which the Warren fastener is used and that modifying the head of the Warren fastener as suggested by the Examiner would render the shank of the Warren fastener unsatisfactory for its intended purpose. App. Br. 21-22.

The issues presented by this appeal include:

Has Appellant shown the Examiner erred in determining that it would have been obvious to modify the head of Warren's fastener to make it flexible?

Rejection based on Bays and Warren

The Examiner found that Bays discloses a "fastener that has all of the claimed structure including being made out of the same material as the claimed invention and intended to repair torn meniscus tissue," and that Bays discloses a flexible head member having a thickness of 0.025 inches that would allow the head to "curve or flex when the rivet is pressed against the tissue to deform to match the same shape of the tissue at least to some extent." Ans. 14. The Examiner further determined that if it is found that the head of Bays is not flexible, it would have been obvious to modify Bays to find the optimum dimensions, as suggested by Bays and Warren. Ans. 14-15.

Appellant argues that the Examiner's articulation of a reason to combine the reference teachings in the manner claimed is inadequate because "it does not state why one of ordinary skill in the art would want to

modify the head of Bays to flex.” App. Br. 31. Appellant also argues that even if the reference teachings were combined, the combination would not result in the claimed invention having a flexible fastener head. App. Br. 32. Appellant further argues that the modification proposed by the Examiner would require the head of the rivet to be more flexible to such an extent that the rivet would no longer be insertable using the method of Bays. Reply Br. 15. Appellant further argues that the combination of Bays and Warren fails to render obvious numerous other claim elements.

The issues presented by this appeal include:

Has Appellant shown the Examiner erred in finding that the head of the tack member of Bays is flexible, as claimed?

Has Appellant shown the Examiner erred in concluding that the combined teachings of Bays and Warren render obvious all of the argued claim elements?

Rejection based on either Warren or Bays and Warren in view of either Duncan, or Chisholm, or Paravano

Appellant argues that Chisholm and Paravano are non-analogous art. App. Br. 39. Appellant further argues that certain of these rejected dependent claims are patentable because Duncan fails to teach a plurality of projections positioned in a radially-staggered configuration along the shaft. App. Br. 40-43.

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The issues presented by this appeal include:

Has Appellant shown the Examiner erred in determining that the subject matter of these rejected claims would have been obvious in view of Bays and Warren and either Duncan, or Chisholm, or Paravano because Chisholm and Paravano are non-analogous art?

Has Appellant shown the Examiner erred in determining that the combination of Bays, Warren, and Duncan would have rendered obvious a rivet having a plurality of projections positioned in a radially-staggered configuration along the shaft?

*Rejection based on either Warren or Bays and Warren in view of
Simons*

The Examiner concluded that “it would have been obvious to one of ordinary skill in the art to further modify the prior art to use a spherical recess and cooperating driver as taught by Simons as an obvious equivalent way of mating the driver to the fastener to force the fastener into place.”

Ans. 16.

Appellant argues that the Examiner erred because Simons fails to teach that the driver head is equivalent to the applicator configuration taught by Bays, and thus the driver of Simons cannot be cited as an obvious equivalent. App. Br. 44.

The issues presented by this appeal include:

Has Appellant shown the Examiner erred in determining that it would have been obvious to modify the tack member of Bays to use a spherical recess and cooperating driver as taught by Simons?

PRINCIPLES OF LAW

Written Description

“[T]he purpose of the written description requirement is to ‘ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.’” *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed. Cir. 2004) (quoting *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000)). This requirement protects the quid pro quo between inventors and the public, whereby the public receives “meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002).

To satisfy the written description requirement, a patent applicant must “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention [as now claimed].” *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

“[T]he written description requirement is satisfied by the patentee’s disclosure of ‘such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.’” *Enzo Biochem*,

Inc. v. Gen-Probe Inc., 323 F.3d 956, 969 (Fed. Cir. 2002) (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)). In deciding the issue of written description, the specification as a whole must be considered. *In re Wright*, 866 F.2d 422, 425 (Fed. Cir. 1989).

On the one hand, the claimed subject matter need not be described “*in haec verba*” in the original specification in order to satisfy the written description requirement. *In re Wright*, 866 F.2d 422, 425 (Fed. Cir. 1989). Rather, “the specification as originally filed must convey clearly to those skilled in the art the information that the applicant has invented the specific subject matter later claimed.” *Id.* at 424 (quoting *In re Smith*, 481 F.2d 910, 914 (CCPA 1973)).

On the other hand, the written description requirement is not necessarily met as a matter of law because the claim language appears *in ipsius verbis* in the specification. *Enzo Biochem*, 323 F.3d at 968 (“Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed.”). “The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.” *Id.* (citation omitted).

Indefiniteness

The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety*

Travel Chairs, Inc., 806 F.2d 1565, 1576 (Fed. Cir. 1986) (citations omitted).

Obviousness

“Section 103 forbids issuance of a patent when ‘the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.’” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). *See also KSR*, 550 U.S. at 406-07 (“While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.”)

In *KSR*, the Supreme Court emphasized “the need for caution in granting a patent based on the combination of elements found in the prior art,” *id.* at 415, and discussed circumstances in which a patent might be determined to be obvious. In particular, the Supreme Court emphasized that “the principles laid down in *Graham* reaffirmed the ‘functional approach’ of *Hotchkiss*, 11 How. 248.” *Id.* (citing *Graham*, 383 U.S. at 12), and reaffirmed principles based on its precedent that “[t]he combination of

familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 416. The operative question in this “functional approach” is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 417.

FINDINGS OF FACT

We find that the following enumerated findings are supported by at least a preponderance of the evidence. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

Appellant’s Original Disclosure

1. Appellant’s original disclosure described with respect to a first embodiment that “[t]he disc 18, as shown in Figure 4, is sufficiently flexible so as to be able to conform to the angle of the meniscus M.” Spec. 6:31-33.
2. Appellant’s original disclosure similarly described with respect to a second embodiment that “[t]he force on the face 135 of the driver 130 causes the disc 118 to deform so as to conform to the surface of the meniscus, as shown in figures 6 and 7.” Spec. 7:29-31.
3. Figure 3 of Appellant’s original disclosure shows a meniscus having a concave surface and flexible discs 18 contacting the meniscus tissue, such that one skilled in the art would understand that for the discs 18 to conform to this tissue, as disclosed, the

discs would necessarily curve and the top surface of each disc would be concave.

4. Figures 4 and 5 of Appellant's original disclosure show embodiments of the rivet in which the flexible member is significantly thinner than the length of the shaft and in which the flexible member is only slightly larger in diameter than the diameter of the shaft. One skilled in the art, viewing the depictions of the rivets in these figures, would understand that the mass of the flexible member is considerably less than the mass of the shaft. This would correspondingly mean that the surface area-to-mass ratio of the flexible member would be larger than the same ratio of the shaft.
5. Figure 7 of Appellant's original disclosure shows that upon insertion of the rivet, the member 118 is disposed at an angle relative to the mid-longitudinal axis of the shaft, such that one portion of the member forms an acute angle with the axis and another portion of the member forms an obtuse angle with the axis. Spec., figure 7; see also App. Br., Exhibit D.
6. Appellant's Specification describes that "[t]he rivet 10 is made of a soft flexible plastic which is biodegradable and totally absorbable within the body, such as polyglycolic acid or carbon composite, or any similarly biodegradable, bioabsorbable and otherwise biologically safe material." Spec. 6:27-31.

7. Appellant's Specification describes the dimensions of the rivet 10 as follows: "[t]he overall length of the rivet 10 is approximately 8mm [0.315 inch], the shaft 12 of the rivet has an outside diameter of about 2mm [0.079 inch] and the outside diameter of the rear disc member is about 2.5mm [0.098 inch]." Spec. 8:3-6. Appellant's Specification further describes that "the passageway 124 of the rivet 100 is about 1.25mm [0.049 inch] in diameter." Spec. 8:11-12. Appellant's Specification does not provide a thickness for the rear disc member.

Warren

8. Warren discloses a fastener 100 adapted to attach soft tissues to bone and bone-like structures comprising a shank 105 and a head 110. Head 110 has a thickness of 0.069 inches. Warren, col. 3, ll. 35-40. Warren discloses that its fastener has a top end surface 150 that is rounded, and teaches that the rounded outer edge is "to minimize any interference by the fastener with other bodily parts." Warren, col. 6, ll. 22-25; fig. 1.
9. Warren discloses that a fillet 161 is provided at the junction of shank portion 115 and the lower surface 160 of head 110. Warren, col. 3, ll. 40-42.
10. Warren describes that in use, a ligament 200 is positioned against the bone 300 and then a guide wire 400 is passed through ligament 200 and into bone 300. A cannulated drill 500 is passed down the guide wire 400 and drilled through ligament 200 and into bone 300

and then the drill is removed. The fastener 100 is then loaded onto guide wire 400 and a hollow driver 600 is coaxially fitted onto the free top end of guide wire 500 and is used to drive the fastener 100 into the bone 300 so that the head of the fastener securely captivates the ligament against the bone. The hollow driver 600 and guide wire 400 are then withdrawn, leaving fastener 100 behind. Warren, figs. 4-8 and col. 3, l. 60 – col. 5, l. 37.

11. Warren discloses that the hollow driver is “used to successively strike the head of the fastener so as to drive the shank of the fastener through the soft tissue and into the bone, with the head of the fastener engaging the soft tissue and captivating it against the bone.” Warren, col. 2, ll. 13-18.
12. As shown in figure 8 of Warren, when the fastener is installed such that it captivates the ligament 200 against the bone 300, the head 110 of fastener remains perpendicular to the longitudinal axis of the shaft, the bottom surface of the head 110 remains flat, and the top surface of the head 110 does not appear to be curved or concave. Warren, fig. 8.

Bays

13. Bays discloses an apparatus for repairing a meniscal tear during arthroscopic surgery of the knee. Bays, col. 1, ll. 12-14.
14. In particular, Bays discloses a repair tack 10 for deployment in tissue by use of an applicator 20 and a needle 30. Bays, col. 4, ll. 6-8.

15. The tack 10 has a shaft portion 14 and a flange-like cross bar grip portion 15 having rounded corners, and a bore 13 extending longitudinally through the entire length of the tack 10. Bays, col. 4, ll. 16-23; fig. 3. The shaft portion 14 includes a plurality of barb members 16 disposed in axial sequence along its periphery. Bays, col. 4, ll. 29-32. The rearward facing surface 17 of each barb member 16 is oriented to preclude rearward movement and resulting inadvertent removal of the tack member 10 from the tissue into which the tack member has been deployed. Bays, col. 4, ll. 48-52.
16. Bays discloses that the tack can be formed from an absorbable polymer or copolymer, preferably derived from glycolic and lactic acids, such as polyglycolide. Bays, col. 3, ll. 33-41 and col. 5, ll. 40-51.
17. The Examiner found that Bays teaches a fastener that is made out of the same material as Appellant's rivet. Ans. 14. Appellant does not rebut this finding. App. Br., *passim*.
18. Bays discloses that the overall length of the tack member is 0.345 inch and the thickness of the cross bar grip portion 15 parallel to the axis of bore 13 is 0.025 inch. Bays, col. 7, ll. 5-14.
19. Bays discloses that applicator 20 has a hollow interior for receiving needle 30 in axially slidable engagement. Bays, col. 5, ll. 3-5. The forward end 21 of applicator 20 has a J-shaped configuration to define a slot 23 for receiving the cross-bar grip portion 15 of tack

member 10. Bays, col. 5, ll. 5-8. A forward lip 25 extends across the slot 23 terminating a short leg of the J-configuration and serves to restrain grip portion 15, when it is in slot 23, against movement longitudinally of applicator 20 and tack member 10 and against twisting or rotation about any axis extending vertically (as viewed in figure 2). Bays, col. 5, ll. 12-18.

20. In use, the apparatus is assembled prior to insertion in the body joint by placing the cross-bar portion 15 into slot 23 at the forward end of applicator 20. Needle 30 is then slidably passed through the hollow applicator 20 and bore 13 in tack member 10, and threaded connectors 27 and 32 are tightened. With the tack member firmly supported in slot 23 and by needle 30, the device may be inserted into the joint cavity. Bays, col. 6, ll. 25-34. The point of the needle 30 is then placed into contact with the tissue and force is applied to the applicator and needle (locked together by threaded engagement) to cause the needle and tack to penetrate the torn meniscus portions to the desired depth. The connectors 27 and 32 are disengaged and the needle is withdrawn from the tack member 10 into the applicator 20. The cross bar grip portion 15 is then removed from slot 23 by rotating the forward end of applicator 20 downwardly, transversely of the axis of bore 13. Applicator 20 is then withdrawn from tack 10, leaving tack 10 firmly secured within the torn meniscus portions. Bays, col. 6, ll. 36-50.

Duncan

21. Duncan discloses mesh tissue fasteners for fastening together portions of tissue in surgical procedures. Duncan, col. 1, ll. 7-8. Duncan discloses that each leg 66E of the fastening member defines on its exterior along at least a portion of its length a plurality of barbs 80E which are each angled rearwardly away from the leg distal end 70E. Duncan, col. 11, ll. 21-24; figs. 8, 9. The barbs are arranged in groups of four barbs at spaced longitudinal locations along the length of each leg 66E with the barbs in each group of four barbs being equally spaced about the periphery of each leg 66E. Duncan, col. 11, ll. 26-30.

Simons

22. Simons discloses a socket 36 having “four concave curved surfaces 38 which extend from the flat face 40 of the screwhead 34 and blend into a generally spherical surface 42 at the base of the socket 36.” Simons, col. 3, l. 15-19; figs. 4, 6.

ANALYSIS

New Matter Objection and Written Description Rejection

1) flexible member at least in part concave or curved

The Examiner rejected independent claims 29, 60, and 100 and their respective dependent claims, and also dependent claims 33, 105, 148, 183, 214, and 245 because “[t]here appears to be no support in the written

description as originally disclosed for the flexible member to be at least partially concave or curved.” Ans. 8.

Appellant contends that it is well known to those skilled in the art of orthopedic surgery that the surface of the meniscus is curved, and thus the disclosure in Appellant’s Specification that the flexible member is able to conform to the surface of the meniscus, would be understood by one skilled in the art to be a disclosure that the flexible member is at least in part curved and concave when in contact with the tissue. App. Br. 9-10, 14-15.

The Examiner responded that the requirement the flexible member is at least in part curved or concave when in contact with the tissue “does not further limit the structure of the rivet itself” because Appellant is basing patentability on one specific intended use and one specific location when the device is not limited to use in one specific situation. Ans. 20.

We disagree with the Examiner’s claim interpretation. Each of the above-identified claims contains language requiring the flexible member to be at least in part curved or concave *when said flexible member is in contact with the tissue*. This language imparts a structural limitation on the rivet in that it requires that the rivet has a flexible member that is made of a material and in a configuration that renders it capable of conforming to the tissue and, in particular, that renders it capable of assuming a specific shape when in contact with the tissue.

The issue before us for purposes of the written description requirement is not a question of how much weight to give to these limitations of the claims. Rather, the issue before us is whether the original

disclosure provides an adequate description of such a flexible member to those skilled in the art as of the filing date.

Appellant's original disclosure described that the disc is sufficiently flexible so as to be able to conform to the surface of the meniscus (Facts 1, 2). Based on the surface of the meniscus shown in figure 3, one skilled in the art would understand that for the discs to conform to this tissue, the discs would necessarily curve and the top surface of each disc would be concave (Fact 3).

As such, we find that Appellant's disclosure contains adequate written descriptive support for the flexible member being at least in part concave or curved when in contact with the tissue in which the rivet is inserted, as called for in claims 29, 60, and 100 and their respective dependent claims⁴, and also in dependent claims 33, 105, 148, 183, 214, and 245.

2) flexible member having a greater surface area to mass ratio than the shaft and flexible member having a smaller mass than the mass of the shaft

The Examiner rejected dependent claims 34, 65, 106, 149, 184, 215, and 246 because "[t]here appears to be no support in the written description as originally disclosed for the flexible member to have a greater surface area to mass ratio than the shaft." Ans. 8. The Examiner also rejected dependent claims 35, 66, 107, 150, 185, 216, and 247 because "[t]here appears to be no

⁴ Claims 30-59 depend from claim 29; claims 61-99 depend from claim 60; and claims 101-143 depend from claim 100.

support in the written description as originally disclosed for the flexible member to have a smaller mass than the mass of the shaft.” Ans. 8.

Appellant contends that the dimensions of the rivet depicted in figure 4 support these claim limitations. App. Br. 10-11, 15-16 (citing to Exhibit B). The Examiner responds that the figure is not sufficiently detailed to show possession of the claim limitation and that the Appellant’s argument is flawed because it relies on mathematical calculations of relative dimensions based on drawings that are not drawn to scale. Ans. 18-19.

While we acknowledge that Appellant’s drawings may not be drawn to scale, we find that Appellant’s original figures convey with reasonable clarity that he was in possession of the flexible member as now claimed. Appellant’s Figures 4 and 5 show embodiments of the rivet in which the flexible member is significantly thinner than the length of the shaft and in which the flexible member is only slightly larger in diameter than the diameter of the shaft, such that one skilled in the art, viewing the depictions of the rivets in these figures, would understand that the mass of the flexible member is considerably less than the mass of the shaft. This would correspondingly mean that the surface area-to-mass ratio of the flexible member would be larger than the same ratio of the shaft (Fact 4).

As such, we find that Appellant’s disclosure contains adequate written descriptive support for the flexible member having a greater surface area-to-mass ratio than the shaft, as called for in claims 34, 65, 106, 149, 184, 215, and 246, and having a smaller mass than the mass of the shaft, as called for in claims 35, 66, 107, 150, 185, 216, and 247.

3) *portions of the flexible member formed at acute and obtuse angles to the shaft*

The Examiner rejected independent claims 211 and 293 and their respective dependent claims, and also dependent claims 145, 275, and 285 because “[t]here appears to be no support in the written description as originally disclosed for the flexible member to be formed at an acute angle to the shaft.” Ans. 9. The Examiner similarly rejected independent claims 144, 211, and 293 and their respective dependent claims, and also dependent claims 274 and 284 because “[t]here appears to be no support in the written description as originally disclosed for the flexible member to be formed at an acute [*sic*, obtuse] angle to the shaft.” Ans. 9.

Appellant contends that the Examiner misconstrued the claim language and that the claims at issue require only that the rivet is deformable to “form” the acute or obtuse angles upon insertion of the rivet into the meniscus and that this limitation is supported in figure 7. App. Br. 11-13, 16-17 (citing to Exhibit D).

The Examiner responds that because the limitations at issue are not limited in the claim to “when the flexible member is in contact with tissue,” the recitations about the flexible member forming acute and obtuse angles are positive structural limitations of the device before use, which limitations are not supported by the original disclosure. Ans. 19.

Independent claim 211 recites, in part:

a member proximate said trailing end of said shaft, said member having a top, a bottom opposite said top, and an outer perimeter, *said bottom adapted to contact tissue upon insertion of said rivet into the tissue*, at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft, at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft.

App. Br., Claims Appx., Claim 211 (emphasis added). Claims 144 and 145 contain similar claim language.

Independent method claim 293 similarly recites, in part, the step of:

inserting the rivet into the tissue *until the bottom of the member contacts the tissue*, at least a first portion of the bottom adjacent to the outer perimeter of the member being at an acute angle relative to the mid-longitudinal axis of the shaft, at least a second portion of the bottom adjacent to the outer perimeter of the member being at an obtuse angle relative to the mid-longitudinal axis of the shaft.

App. Br., Claims Appx., Claim 293 (emphasis added). Claims 274 and 275 and claims 284 and 285 contain similar claim language.

A person skilled in the art would understand this claim language, when read in light of Appellant's Specification, to call for the first portion of the bottom to be at an acute angle and a second portion of the bottom to be at an obtuse angle relative to the mid-longitudinal axis of the shaft *when the bottom is in contact with the tissue upon insertion of the rivet into the tissue*. As noted by Appellant, figure 7 of Appellant's original disclosure shows that upon insertion of the rivet, the member 118 is disposed at an angle relative

to the mid-longitudinal axis of the shaft, such that one portion of the member forms an acute angle with the axis and another portion of the member forms an obtuse angle with the axis (Fact 5).

As such, we find that Appellant's disclosure contains adequate written descriptive support for the flexible member being formed at an acute angle to the shaft," as called for in independent claims 211 and 293 and their respective dependent claims⁵, and also dependent claims 145, 275, and 285, and for the flexible member being formed at an obtuse angle to the shaft, as called for in independent claims 144, 211, and 293 and their respective dependent claims⁶, and also dependent claims 274 and 284.

Indefiniteness Rejection

In a prior Answer dated December 1, 2005, the Examiner rejected claims 29-300 as being indefinite because "[i]t is not clear what the metes and bounds of the claims are since the claim language noted above has no clear support in the specification as originally filed." Examiner's Answer, mailed December 1, 2005, pp. 6-7. A prior panel of the Board determined that "[t]he rejection under [the] second paragraph is merely a statement that the Examiner is unclear what weight to give the purported new matter, and does not state how the claims do not meet the requirements of 35 U.S.C. § 112, second paragraph." Prior Board Panel Remand dated November 14,

⁵ Claims 212-241 depend from claim 211, and claims 294-300 depend from claim 293.

⁶ Claims 145-175 depend from claim 144.

2007, p. 4. The prior panel thus remanded this case to the Examiner, in part, to further consider the rejection under 35 U.S.C. § 112, second paragraph, and if maintained, “to explicitly address each claim and explain why the claim does not meet the requirements of 35 U.S.C. § 112, second paragraph.” *Id.* The Examiner then provided a Supplemental Examiner’s Answer, dated February 19, 2008, in which the Examiner added that since there appears to be no support in the written description as originally disclosed for the offending claim language, “it is not clear how much weight to give this language.” Ans. 10-12.

The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986) (citations omitted). The Supplemental Answer, mailed February 19, 2008, fails to provide a clear explanation of why those skilled in the art would be unable to understand what is being called for in the claims at issue in this rejection. Rather, the Examiner’s explanation is based on a lack of evidence in the original disclosure that Appellant had possession of the invention at the time of filing, which is unrelated in this case to whether a person skilled in the art would understand what is being claimed. As such, we agree with Appellant that the rejection under 35 U.S.C. § 112, second paragraph, is improper.

Obviousness Rejections

Rejection of claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, and 300 under § 103(a) over Warren

Warren discloses a fastener having a head portion and a shank portion, where the head portion is 0.069 inch, and a fillet is provided between the head portion and the shaft portion, to enable the fastener withstand successively strikes by a driver so as to drive the shank of the fastener through soft tissue and into bone (Facts 8-11). The process for inserting Warren's rivet through tissue and into a hole in the bone appears to require a somewhat rigid head portion to withstand the strikes from the driver and impart the force from such strikes to the shaft so as to force the shaft into the bone. Further, as shown in figure 8 of Warren, when the fastener is installed such that it captivates the ligament against the bone, the head portion of the fastener remains perpendicular to the longitudinal axis of the shaft, the bottom surface of the head remains flat, and the top surface of the head does not appear to be curved or concave (Fact 12).

As such, we do not understand Warren to disclose a head portion that is flexible (1) so as to conform to the surface of the tissue in which the fastener is inserted, as called for in independent claims 29, 60, and 283, or (2) so as to be at least in part curved or concave when the flexible member is in contact with the tissue, as called for in independent claims 29, 60, and 100, or (3) so that at least a portion of the outer perimeter is flexible relative

to the shaft when the fastener is inserted into the tissue, as called for in independent claim 176, or (4) so that at least a portion of the bottom forms an included angle relative to the mid-longitudinal axis of the shaft that is lesser or greater than 90 degrees, as called for in independent claims 144, 211, and 293. We also do not understand the disclosure of Warren to include a head portion that is moveable relative to the shaft portion between an undeployed position and a deployed position of different shapes, as called for in independent claims 242 and 273.

The question that remains is whether the Examiner erred in concluding that it would have been obvious to modify the head portion of Warren's fastener to make it flexible as claimed. We find Appellant's arguments on this issue persuasive. Because the head portion of Warren's fastener must be capable of withstanding strikes from the driver and must be capable of transmitting the force of those strikes to the shaft, we do not see why one having ordinary skill in the art would have been led to modify Warren's head portion to make it as flexible as set forth in Appellant's independent claims.

The Examiner found that "[m]aking the head of the fastener less obtrusive so that it is flush with the tissue surface is a well-recognized problem in the art" and that "[r]educing the size of the head would provide a smooth continuous surface, thereby insuring that nothing would be caught on the extending rivet head and be damaged." Ans. 22-23. This rationale begs the question of whether one having ordinary skill in the art could reduce the profile of the head portion and still design a head portion that

would be rigid enough to withstand strikes from the driver and impart the force of the strikes to the shaft portion. In other words, it does not necessarily flow from a reduction in the thickness of the head portion that the claimed flexibility of the head portion would result since the intended use of Warren's fastener required it to be capable of being pounded into bone. We do not know from the evidence before us whether, assuming a reason exists to reduce the profile of the head portion of Warren, such a reduction in the thickness of the head would have led to the flexible member as called for in each of the independent claims. As such, we cannot sustain the Examiner's rejection of the claims under § 103 based on Warren alone.

Rejection of claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, and 256-300 under § 103(a) over Bays and Warren

Group 1: Claims 29-31, 33-37, 40, 41, and 44-59

Appellant argues claims 29-31, 33-37, 40, 41, and 44-59 as a group. App. Br. 32. We select claim 29 as representative, and the remaining claims of Group 1 stand or fall with claim 29. 37 C.F.R. § 41.37(c)(1)(vii) (2009). The Examiner found that the head portion (cross bar grip portion 15) of Bays is sufficiently flexible so that it would curve or flex when the rivet is pressed against the tissue to deform and match the same shape of the tissue at least to some extent. Ans. 14.

Appellant argues that neither Bays nor Warren teaches or suggests a tissue rivet having a flexible member at the trailing end, the flexible member

being adapted to “deform so as to conform to the surface of the tissue in which said rivet is inserted,” and being “at least in part curved when said flexible member is in contact with the tissue.” App. Br. 32.

Bays discloses a tack member 10 for deployment in tissue to repair a meniscal tear (Facts 13, 14). The tack member 10 includes a cross bar grip portion 15 made out of the same material as Appellant’s flexible member (Facts 6, 16, and 17). Further, overall length of the tack member of Bays and the Appellant’s rivet are similar (Facts 7, 18), while the cross bar grip portion 15 in Bays is substantially shorter, only 0.025 inch thick (Fact 18). Based on these facts, we find that the Examiner’s finding that the cross bar grip portion 15 is flexible enough to deform so as to conform to the surface of the tissue in which said rivet is inserted and is flexible enough so as to be at least in part curved when the flexible member is in contact with the tissue, is supported by a preponderance of the evidence. Where, as here, the Patent Office has reason to believe that a functional limitation is an inherent characteristic of the prior art, Appellant has the burden to show that the prior art does not possess that characteristic. *See In re Best*, 562 F.2d 1252, 1254-55 (CCPA 1977) (quoting *In re Swinehart*, 439 F.2d 210, 212-13 (CCPA 1971); *see also In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) (“when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.”)).

Appellant contends that the head portion of the tack member of Bays must be rigid enough to withstand axial movement or twisting or rotation

about any vertical axis, and thus cannot be fairly said to be sufficiently flexible within the scope of Appellant's claimed invention. App. Br. 32. Appellant has not persuaded us that the applicator of Bays requires a rigid cross bar grip portion.

As disclosed in Bays, the tack member is captured by forward lip 25 and supported in slot 23 and by needle 30 before and during insertion of the device into the joint cavity (Fact 19). Slot 23 provides support along the bottom edge and the proximal surface of the cross bar grip portion 15, forward lip 25 provides support along the distal surface of the cross bar grip portion 15, and needle 30 provides support through the center of the cross bar grip portion 15 (Fact 20), so that a rigid cross bar grip portion is not required to use the tack member 10 with the applicator 20 and needle 30 of Bays. As such, we find that Bays discloses a tack member having a cross bar grip portion 15 that is flexible such that it is adapted to deform so as to conform to the surface of the tissue in which the tack member is inserted and the grip portion 15 being at least in part curved when the grip portion 15 is in contact with the tissue.

Appellant has also failed to persuade us that the Examiner erred in concluding that it would have been obvious, based on the combined teachings of Bays and Warren, to reduce the thickness of the cross bar grip portion 15 of Bays even further to find the optimum thickness and make the head less obtrusive and more flexible so that it is flush with the surrounding tissue. Ans. 14-15. In particular, Appellant argues that the Examiner's statement of motivation is unsupportable because it does not state why one

of ordinary skill in the art would want to modify the head of Bays to flex. App. Br. 31. Having found *supra* that Bays discloses a cross bar grip portion 15 that is capable of flexing, we find the Examiner's explanation for why one having ordinary skill in the art would have been led to further reduce the thickness of the head, i.e., to make the head less obtrusive and flush with the surrounding tissue, provides a rationale articulation of why one would have been led to further modify the tack member of Bays.

Appellant further argues that the combination of Bays and Warren is in error because the combination teaches away from a flexible head portion. As we found *supra*, due to the support provided to the cross bar grip portion 15 by the applicator 20 and needle 30 of the assembly of Bays, we find that the tack member 10 of Bays is capable of operating as intended with a flexible cross bar grip portion 15.

As such, we are not persuaded that the Examiner erred in concluding that the subject matter of claim 29 would have been obvious in view of Bays and Warren, and we will sustain the rejection of claim 29 under § 103. Claims 30, 31, 33-37, 40, 41, and 44-59 fall with claim 29.

Group 2: Claim 32

Claim 32 calls for the flexible member to have an outer edge that is beveled. Appellant argues that neither Bays nor Warren teaches or suggests such a configuration. App. Br. 33. Bays discloses that the top surface of the cross bar grip portion 15 has rounded corners (Fact 15). Warren likewise discloses that its fastener has a top end surface 150 that is rounded, and teaches that the rounded outer edge is "to minimize any interference by the

fastener with other bodily parts” (Fact 8). A beveled object is one that is “cut at an inclination that forms an angle other than a right angle.” *The American Heritage Dictionary*, Second College Ed. (1982). While a rounded corner is not identical to a beveled corner, both types of surface configurations achieve the same purpose, to avoid a sharp edge and to provide a lower profile where two surfaces meet. Appellant has not persuaded us that the Examiner erred in concluding that a flexible member having a beveled outer edge would have been obvious in view of the disclosures in Bays and Warren of fasteners having head portions with rounded outer surfaces, and the teaching in Warren that it was known in the art to round the corners to avoid interference. The use of a beveled edge in place of a rounded edge is nothing more than the predictable use of prior art elements according to their established function. *KSR*, 550 U.S. at 417. As such, we will sustain the rejection of claim 32 under § 103.

Group 3: Claims 60-63, 65-69, 72, 73, 76-86, and 89-99

Appellant argues claims 60-63, 65-69, 72, 73, 76-86, and 89-99 as a group. App. Br. 33. We select claim 60 as the representative claim, and the remaining claims of Group 3 stand or fall with claim 60. 37 C.F.R. § 41.37(c)(1)(vii). Claim 60 calls for the flexible member to be “adapted to deform so as to conform to the surface of the tissue in which said rivet is inserted” and calls for “said top of said flexible member being at least in part concave when said flexible member is in contact with the tissue.” Appellant relies on the same arguments made for claim 29 to argue that neither Bays nor Warren has a flexible head as called for in claim 60. For the same

reasons provided *supra* in our analysis of claim 29 (Group 1), we find Appellant's arguments unpersuasive. In particular, we find that the cross bar grip portion 15 of the tack member of Bays is sufficiently flexible so as to conform to the tissue in which it is inserted, and as such, it is capable of assuming a concave configuration when in contact with the tissue. As such, we will sustain the rejection of claim 60 under § 103, and claims 61-63, 65-69, 72, 73, 76-86, and 89-99, which fall with claim 60.

Group 4: Claim 64

Claim 64 calls for the flexible member to have an outer edge that is beveled. Appellant presents the same arguments to rebut the obviousness rejection of claim 64 as were made for patentability of claim 32. For the reasons provided *supra* in our analysis of claim 32 (Group 2), we find these arguments equally unpersuasive of error in the Examiner's rejection of claim 64. As such, we will sustain the rejection of claim 64 under § 103.

Group 5: Claims 100-103, 105-111, 114, 115, 118-130, and 133-143

Appellant argues claims 100-103, 105-111, 114, 115, 118-130, and 133-143 as a group. App. Br. 33-34. We select claim 100 as the representative claim, and the remaining claims of Group 5 stand or fall with claim 100. 37 C.F.R. § 41.37(c)(1)(vii). Claim 100 calls for the flexible member to be "at least in part curved when said bottom of said flexible member contacts the tissue." Appellant relies on the same arguments made for claim 29 to argue that neither Bays nor Warren has a flexible member as called for in claim 100. For the same reasons provided *supra* in our analysis of claim 29 (Group 1), we find Appellant's arguments unpersuasive. In

particular, we find that the cross bar grip portion 15 of the tack member of Bays is sufficiently flexible so as to conform to the tissue in which it is inserted, and as such, it is capable of assuming a curved configuration when in contact with the tissue. As such, we will sustain the rejection of claim 100 under § 103, and claims 101-103, 105-111, 114, 115, 118-130, and 133-143, which fall with claim 100.

Group 6: Claim 104

Claim 104 calls for the flexible member to have an outer edge that is beveled. Appellant presents the same arguments to rebut the obviousness rejection of claim 104 as were made for patentability of claim 32. For the reasons provided *supra* in our analysis of claim 32 (Group 2), we find these arguments equally unpersuasive of error in the Examiner's rejection of claim 104. As such, we will sustain the rejection of claim 104 under § 103.

Group 7: Claims 144-153, 156, and 159-175

Appellant argues claims 144-153, 156, and 159-175 as a group. App. Br. 34. We select claim 144 as the representative claim, and the remaining claims of Group 7 stand or fall with claim 144. 37 C.F.R. § 41.37(c)(1)(vii). Claim 144 calls for at least a portion of the bottom of the flexible member to form "an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees." Appellant relies on the same arguments made for claim 29 to argue that neither Bays nor Warren has a flexible member as called for in claim 144. For the same reasons provided *supra* in our analysis of claim 29 (Group 1), we find Appellant's arguments unpersuasive. In particular, as we found *supra*, the head portion of Bays's

tack member is sufficiently flexible so as to conform to the tissue into which it is inserted. This flexibility would cause the head portion to cant, or deviate from its original perpendicular orientation relative to the mid-longitudinal axis of the shaft portion, upon insertion of the tack member into the tissue. As such, we will sustain the rejection of claim 144 under § 103, and claims 145-153, 156, and 159-175, which fall with claim 144.

Group 8: Claims 176-188, 191, 194-210

Appellant argues claims 176-188, 191, 194-210 as a group. App. Br. 34-35. We select claim 176 as the representative claim, and the remaining claims of Group 8 stand or fall with claim 176. 37 C.F.R. § 41.37(c)(1)(vii). Claim 176 calls for a flexible member where at least a portion of its outer perimeter is “flexible relative to said shaft when said rivet is inserted into the tissue.” Appellant relies on the same arguments made for claim 29 to argue that neither Bays nor Warren has a flexible member as called for in claim 176. For the same reasons provided *supra* in our analysis of claim 29 (Group 1), we find Appellant’s arguments unpersuasive. In particular, we find that the cross bar grip portion 15 of the tack member of Bays is sufficiently flexible so as to conform to the tissue in which it is inserted. As such, we will sustain the rejection of claim 176 under § 103, and claims 177-188, 191, 194-210, which fall with claim 176.

Group 9: Claims 211-219, 222, and 225-241

Appellant argues claims 211-219, 222, and 225-241 as a group. App. Br. 35. We select claim 211 as the representative claim, and the remaining claims of Group 9 stand or fall with claim 211. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 211 calls for at least a first portion of the bottom of the flexible member adjacent the outer perimeter to be “at an acute angle relative to the mid-longitudinal axis of said shaft” and at least a second portion of the bottom of the flexible member adjacent the outer perimeter to be “at an obtuse angle relative to the mid-longitudinal axis of said shaft.” Appellant relies on the same arguments made for claim 29 to argue that neither Bays nor Warren has a flexible member as called for in claim 211. For the same reasons provided *supra* in our analysis of claim 29 (Group 1) and claim 144 (Group 7), we find Appellant’s arguments unpersuasive. In particular, as we found *supra*, the head portion of Bays’s tack member is sufficiently flexible so as to conform to the tissue into which it is inserted. This flexibility would cause the head portion to cant, or deviate from its original perpendicular orientation relative to the mid-longitudinal axis of the shaft portion, upon insertion of the tack member into the tissue. As such, we will sustain the rejection of claim 211 under § 103, and claims 212-219, 222, and 225-241, which fall with claim 211.

Group 10: Claims 242-250, 253, and 256-272

Appellant argues claims 242-250, 253, and 256-272 as a group. App. Br. 35. We select claim 242 as the representative claim, and the remaining claims of Group 10 stand or fall with claim 242. 37 C.F.R. § 41.37(c)(1)(vii). Claim 242 calls for a member proximate the trailing end of the shaft to have a first shape in a deployed position and a second, different shape in an undeployed position. Appellant relies on the same arguments made for claim 29 to argue that neither Bays nor Warren has a member as called for in

claim 242. For the same reasons provided *supra* in our analysis of claim 29 (Group 1), we find Appellant's arguments unpersuasive. In particular, as we found *supra*, the head portion of Bays's tack member is sufficiently flexible so as to conform to the tissue into which it is inserted. This flexibility would cause the head portion to assume a first shape in a deployed position, i.e., when the bottom surface is in contact with the tissue, and to assume a second, different shape in an undeployed position. As such, we will sustain the rejection of claim 242 under § 103, and claims 243-250, 253, and 256-272, which fall with claim 242.

Group 11: Claims 273-276, 278-280, and 282

Appellant argues claims 273-276, 278-280, and 282 as a group. App. Br. 35-36. We select claim 273 as the representative claim, and the remaining claims of Group 11 stand or fall with claim 273. 37 C.F.R. § 41.37(c)(1)(vii). Claim 273 is directed to a method and calls for the steps of (1) providing a rivet having a member proximate the trailing end of the shaft, the member having a first shape in a deployed position and a second, different shape in an undeployed position, and (2) moving at least a portion of the member relative to the shaft to the deployed position. Appellant relies on the same arguments made for claim 29 to argue that neither Bays nor Warren discloses the steps of providing a member, or moving at least a portion of the member relative to the shaft, as called for in claim 273. For the same reasons provided *supra* in our analysis of claim 29 (Group 1) and claim 242 (Group 10), we find Appellant's arguments unpersuasive. In particular, as we found *supra*, the head portion of Bays's tack member is

sufficiently flexible so as to conform to the tissue into which it is inserted. This flexibility would cause the head portion to assume a first shape in a deployed position, i.e., when the bottom surface is in contact with the tissue, and to assume a second, different shape in an undeployed position. Bays teaches inserting the tack member into the tissue (Fact 20), and thus discloses moving at least a portion of the member relative to the shaft to the deployed position. As such, we will sustain the rejection of claim 273 under § 103, and claims 274-276, 278-280, and 282, which fall with claim 273.

Group 12: Claim 277

Claim 277 calls for the step of inserting the shaft of the driving instrument into the passageway of the rivet until the face of the driving instrument contacts the top of the member. Appellant argues that neither reference teaches this step because, Warren's fastener is pounded into position, and the repair tack assembly of Bays is assembled by *first* placing the cross bar portion 15 into slot 23 at the forward end of applicator 20, and *then* slidably passing needle 30 through the hollow applicator and bore 13 in tack member 10. App. Br. 36. We agree with Appellant.

The use of the word "until" in the step of claim 277 imparts a temporal context to the claim language, and thus the claim requires that the shaft of the driving instrument is inserted through a passageway in the rivet before the face of the driving instrument contacts the top of the member. Neither Warren nor Bays discloses an assembly in which this step is met, and the Examiner has not provided any articulation of a reason why one having ordinary skill in the art would have been led to modify either

assembly to result in the claimed method. As such, we cannot sustain the rejection of claim 277 under § 103.

Group 13: Claims 281

Claim 281 recites the method step of “inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee.” Appellants argue that neither Warren nor Bays teaches or suggests this step. Bays discloses a tack member that can be used to repair torn meniscal tissue, wherein the leading end of the tack member is inserted into portions of meniscal tissue to repair a tear in the tissue (Facts 13, 14, 20). While Bays does not depict in its figures its tack member actually inserted into the meniscal tissue, or describe explicitly a specific direction in which the leading end of the tack member is inserted into the tissue, there are only two directions in which the leading end of the tack member may be inserted into the meniscal tissue relative to the center of the knee, namely, the leading end may be inserted into the tissue either in a direction toward or in a direction away from the center of the knee. Based on the disclosure in Bays of a tack member for the same purpose of repairing torn meniscal tissue as Appellant’s rivet and the disclosure of its tack member being used in the same manner as Appellant’s rivet to be inserted into portions of the torn tissue, we conclude that it would have been obvious to try inserting the leading end of the tack member into the tissue in a direction away from the center of the knee depending on the location and orientation of the tear. *KSR*, 550 U.S. at 421 (“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable

solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.”).

Group 14: Claims 283-285, 289, 290, and 292

Appellant argues claims 283-285, 289, 290, and 292 as a group. App. Br. 36-37. We select claim 283 as the representative claim, and the remaining claims of Group 14 stand or fall with claim 283. 37 C.F.R. § 41.37(c)(1)(vii). Claim 283 calls for a method including the step of “inserting the rivet into the tissue until the bottom of the flexible member contacts the tissue and the flexible member deforms to conform to the curvature of the tissue adjacent the rivet.” Appellant relies on the same arguments made for claim 29 to argue that neither Bays nor Warren has a flexible member capable of deforming to conform to the curvature of the tissue adjacent the rivet as called for in claim 283. For the same reasons provided *supra* in our analysis of claim 29 (Group 1), we find Appellant’s arguments unpersuasive. In particular, as we found *supra*, the head portion of Bays’s tack member is sufficiently flexible so as to conform to the tissue into which it is inserted. As such, we will sustain the rejection of claim 283 under § 103, and claims 284, 285, 289, 290, and 292, which fall with claim 283.

Group 15: Claims 286 and 287

Similar to claim 277 (Group 12), claim 286 calls for the step of inserting the shaft of the driving instrument into the passageway of the rivet

until the face of the driving instrument contacts the top of the member. For the same reasons provided *supra* in our analysis of claim 277, we will not sustain the rejection of claim 286, and claim 287 which depends therefrom, under § 103.

Group 16: Claim 288

Claim 288 recites that the step of engaging a driving instrument to the rivet (claim 283) includes “snap-fitting the rivet onto a portion of the driving instrument.” Appellant argues that neither Warren nor Bays teaches or suggests such a step. App. Br. 37. The Examiner found that the fastener of Bays is friction fit within the J-shaped arms 26 of the insertion member and determined that “[t]here is no unobviousness to the head being friction fit or snap fit in place.” Ans. 28. We agree with the Examiner.

Bays discloses that a forward lip 25 extends across the slot 23 of applicator 20 and serves to restrain the grip portion 15 of tack member 10, when it is in the slot 23, against movement longitudinally of applicator 20 and tack member 10 and against twisting or rotation about any axis extending vertically (as viewed in Figure 2) (Fact 19). As such, the Examiner’s finding that Bays discloses a friction fit between the grip portion and driving instrument is supported by a preponderance of the evidence. Appellant does not appear to contest this finding.

A friction or press fit is one type of well known mechanical connection for connecting parts. A snap fit is another well known mechanical connection that allows parts to have frequent assembly and disassembly. Appellant has not persuaded us that the Examiner erred in

concluding that modifying the engagement of the cross bar grip portion 15 and slot 23 of Bays from a friction fit to a snap fit would have been obvious. The use of a snap fit would allow the cross bar grip portion 15 to be removed from the slot by rotating the forward end of applicator 20 downwardly, transversely of the axis of bore 13, as disclosed in Bays (Fact 20). Further, the use of snap fit would allow the slot 23 and forward lip 25 of Bays's applicator 20 to perform the same function of restraining certain movements of the grip portion 15, as disclosed in Bays (Fact 19). As such, the use of a snap fit in place of a friction fit to engage the grip portion 15 and applicator 20 in Bays is nothing more than the predictable use of prior art elements according to their established function. *KSR*, 550 U.S. at 417. Thus, we will sustain the rejection of claim 288 under § 103.

Group 17: Claim 291

Similar to claim 281 (Group 13), claim 291 recites the method step of "inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee." Appellant relies on the same argument for patentability of claim 291 as was made for claim 281. For the reasons provided *supra* in our analysis of claim 281, we find that Appellant has failed to show the Examiner erred in concluding that the step of claim 291 would have been obvious in view of Bays and Warren. As such, we will sustain the rejection of claim 291.

Group 18: Claims 293, 294, 296-298, and 300

Appellant argues claims 293, 294, 296-298, and 300 as a group. App. Br. 37-38. We select claim 293 as the representative claim, and the

remaining claims of Group 18 stand or fall with claim 293. 37 C.F.R. § 41.37(c)(1)(vii). Claim 293 calls for a method including the step of “inserting the rivet into the tissue until the bottom of the member contacts the tissue, at least a first portion of the bottom adjacent to the outer perimeter of the member being at an acute angle relative to the mid-longitudinal axis of the shaft, at least a second portion of the bottom adjacent to the outer perimeter of the member being at an obtuse angle relative to the mid-longitudinal axis of the shaft.” Appellant relies on the same arguments made for claim 29 to argue that neither Bays nor Warren has a flexible member capable of deforming upon insertion of the rivet into the tissue so that portions of the member are at angles other than perpendicular to the mid-longitudinal axis of the shaft as called for in claim 293. For the same reasons provided *supra* in our analysis of claim 29 (Group 1) and claim 144 (Group 7), we find Appellant’s arguments unpersuasive. In particular, as we found *supra*, the head portion of Bays’s tack member is sufficiently flexible so as to conform to the tissue into which it is inserted. This flexibility would cause the head portion to cant, or deviate from its original perpendicular orientation relative to the mid-longitudinal axis of the shaft portion, upon insertion of the tack member into the tissue. As such, we will sustain the rejection of claim 293 under § 103, and claims 294, 296-298, and 300, which fall with claim 293.

Group 19: Claim 295

Similar to claim 277 (Group 12), claim 295 calls for the step of inserting the shaft of the driving instrument into the passageway of the rivet

until the face of the driving instrument contacts the top of the member. For the same reasons provided *supra* in our analysis of claim 277, we will not sustain the rejection of claim 295 under § 103.

Group 20: Claim 299

Similar to claim 281 (Group 13), claim 299 recites the method step of “inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee.” Appellant relies on the same argument for patentability of claim 299 as was made for claim 281. For the reasons provided *supra* in our analysis of claim 281, we find that Appellant has failed to show that the Examiner erred in concluding that the step of claim 299 would have been obvious in view of Bays and Warren. As such, we will sustain the rejection of claim 299.

Rejection of claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, and 251-258 under § 103(a) over either Warren or Bays and Warren, and further in view of either Duncan, or Chisholm, or Paravano

Appellant argues claims 38-40, 43, 46-48, 70-73, 75, 78-80, 112-115, 117, 120-122, 154-156, 157-161, 189-191, 193-196, 220-222, 224-227, 251-253, and 255-258 as a group. App. Br. 39-43. We select claim 38 as representative and the remaining claims of the group stand or fall with claim 38. 37 C.F.R. § 41.37(c)(1)(vii). Appellant presents separate arguments for claims 42, 74, 116, 157, 192, 223, and 254. App. Br. 40-43. We address these separately argued claims *infra*.

With regard to group represented by claim 38, Appellant argues that the Examiner erred in rejecting the claims because (1) Chisholm and Paravano are non-analogous art, and (2) these claims depend from an allowable independent claim, or claims dependent therefrom. App. Br. 39-40. We need not reach the issue of non-analogous art raised by Appellant's first argument because the Examiner's rejection was based on a combination of Bays and Warren and *either* Duncan *or* Chisholm *or* Paravano. As such, even if Chisholm and Paravano were found to be non-analogous art, this alone would not be sufficient to show error in the Examiner's rejection based on Bays, Warren, and Duncan. In the second argument, Appellant relies on the arguments made for patentability of independent claims 29, 60, 100, 144, 176, 211, and 242 over Bays and Warren. For the reasons provided *supra*, we found these arguments unpersuasive of error in the Examiner's rejection of the independent claims, and thus for the same reasons, we find these arguments equally unpersuasive of error in the rejection of the group of claims represented by claim 38. As such, we will sustain the rejection of claim 38 and claims 39, 40, 43, 46-48, 70-73, 75, 78-80, 112-115, 117, 120-122, 154-156, 157-161, 189-191, 193-196, 220-222, 224-227, 251-253, and 255-258 falling with claim 38.

With regard to each of claims 42, 74, 116, 157, 192, 223, and 254, Appellant argues that Duncan fails to teach barbs positioned in a radially staggered configuration along said shaft. App. Br. 40-43. Appellant proffers a definition of "stagger" as "marked by an alternating or overlapping pattern." App. Br. 40.

Duncan discloses mesh tissue fasteners having barbs on each leg of the fastening member, where the barbs are arranged in groups of four barbs at spaced, longitudinal locations along the length of each leg with the barbs in each group of four barbs being equally spaced about the periphery of each leg (Fact 21).

The Examiner found that Duncan's barbs are radially staggered at 90 degree intervals around the mid-longitudinal axis of the shaft and overlap each other along the longitudinal axis of the shaft. Ans. 29. The Examiner added that "[t]o any extent [that] appellant's projections are staggered so are the projections of Duncan. Appellant's drawings do not appear to show any configuration that is different from what Duncan shows." *Id.* We agree with the Examiner's interpretation of "radially staggered" to encompass Duncan's rows of four barbs each encircling the leg along the length of the leg.

Appellant's figures show flexible projections 16, 116 disposed about and along the length of shaft 12, 112 in a radially staggered configuration that is the same as the configuration disclosed in Duncan. In particular, figures 1 and 6 of Appellant's disclosure show groups of four flexible projections 16, 116 at spaced longitudinal locations along the length of shaft 12, 112 with the flexible projections 16, 116 in each group of four projections being equally spaced about the periphery of shaft 12, 112 at approximately 90 degree intervals. Spec. 5-7; figs. 1, 6. As such, one skilled in the art would understand the claim language "positioned in a radially staggered configuration along said shaft" when read in view of Appellant's Specification, to include barbs or projections that are equally-spaced at 90

degree intervals radially about the shaft and that overlap each other along the shaft. Thus, Appellant has failed to show the Examiner erred in rejecting claims 42, 74, 116, 157, 192, 223, and 254 under § 103.

Rejection of claims 87, 88, 131, and 132 under § 103(a) over either Warren or Bays and Warren, and further in view of Simons

Claims 87 and 131 call for a rivet having a shaft with a trailing end that includes a depression configured to cooperatively engage a driver instrument. Claims 88 and 132, depend from claims 87 and 131, respectively, and further call for the depression to be spherical.

The Examiner found that Simons discloses a way for a driver to mate with the head of a fastener in which the fastener includes a generally spherical recess in the head, and determined that it would have been obvious to modify the tack member and driver assembly of Bays to use a spherical recess and cooperating driver as taught by Simons as an obvious equivalent way of mating the driver to the fastener to force the fastener into place.

Ans. 16. Appellant argues that the rejection is in error as a matter of law because in order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on Appellant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. App. Br. 44. This argument seems to disregard the recent guidance from the Supreme Court in *KSR* in which the Court instructed that an obviousness determination should use a functional approach which asks "whether the

improvement is more than the predictable use of prior art elements according to their established functions.” 550 U.S. at 417. We agree with the Examiner’s conclusion of obviousness based on the functional approach outlined by the Supreme Court in *KSR*, and Appellant has not persuaded us that the Examiner’s proposed combination was in error.

Appellant separately argued, with regard to claims 87 and 131, that “[t]he machine screw taught by Simmons [*sic*] is not suitable for use as a tissue rivet in a surgical environment” and thus, none of the art cited by the Examiner teaches or suggests “a tissue rivet having a shaft with a trailing end that includes a depression that is configured to cooperatively engage a driver instrument.” App. Br. 44, 45. This argument does not address the proposed combined teachings of the references and amounts to arguing the references individually. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Merck & Co.*, 800 F.2d 1091 (Fed. Cir. 1986); *In re Keller*, 642 F.2d 413 (CCPA 1981). The Examiner did not rely on either Bays or Warren to teach the claimed depression, and the Examiner did not rely on Simons to teach the claimed tissue rivet. As such, Appellant has not persuaded us of error in the Examiner’s rejection of claims 87 and 131 under § 103.

Appellant similarly argued, with regard to claims 88 and 132, that “[t]he machine screw taught by Simmons [*sic*] is not suitable for use as a tissue rivet in a surgical environment” and thus, none of the art cited by the Examiner teaches or suggests “a tissue rivet having a shaft with a trailing

end that includes a depression that is at least in part spherical.” App. Br. 44, 45. For the same reasons as provided *supra*, this individual attack on the references does not persuade us of error in the Examiner’s rejection of claims 88 and 132. Further, we find that the Simons discloses a socket 36 having “four concave curved surfaces 38 which extend from the flat face 40 of the screwhead 34 and blend into a generally spherical surface 42 at the base of the socket 36” (Fact 22), and thus the depression disclosed in Simons is “at least in part spherical” as claimed. As such, we will sustain the rejection of claim 87, 88, 131, and 132 under § 103.

CONCLUSIONS

Appellant has shown the Examiner erred in determining that the original disclosure fails to provide adequate written description of the claimed features and characteristics of the flexible member.

Appellant has also shown the Examiner erred in determining that the claims are indefinite based on the rationale that they contain language not supported by the original disclosure.

Appellant has also shown the Examiner erred in determining that it would have been obvious to modify the head of Warren’s fastener to make it flexible.

Appellant has failed, however, to show the Examiner erred in finding that the head of Bays’s tack member is flexible, as called for in claims 29, 60, 100, 144, 176, 211, 242, 273, 283, and 293.

Appellant has also failed to show the Examiner erred in concluding that the combined teachings of Bays and Warren render obvious a flexible member having an outer edge that is beveled, as called for in claims 32, 64, 104; the step of inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee, as called for in claims 281, 291, and 299; and the step of snap-fitting the rivet onto a portion of the driving instrument, as called for in claim 288.

Appellant has shown, however, that that Examiner erred in concluding that the combined teachings of Bays and Warren render obvious the step of inserting the shaft of the driving instrument into the passageway of the rivet until the face of the driving instrument contacts the top of the member, as called for in claims 277, 286, 287, and 295.

Appellant has failed to show the Examiner erred in determining that the subject matter of claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, and 251-258 would have been obvious in view of Bays and Warren and either Duncan, or Chisholm, or Paravano on the basis that Chisholm and Paravano are non-analogous art.

Appellant has also failed to show the Examiner erred in determining that the combination of Bays, Warren, and Duncan would have rendered obvious a rivet having a plurality of projections positioned in a radially staggered configuration along the shaft.

Appellant has also failed to show the Examiner erred in determining that it would have been obvious to modify the tack member of Bays to use a spherical recess and cooperating driver as taught by Simons.

DECISION

We sustain the following rejections:

- The rejection of claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89, 111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, and 256-276, 278-285, 288-294, and 296-300 under 35 U.S.C. § 103(a) as being unpatentable over Bays and Warren.
- The rejection of claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, and 251-258 under 35 U.S.C. § 103(a) as being unpatentable over either Warren or Bays and Warren, and further in view of either Duncan, or Chisholm, or Paravano.
- The rejection of claims 87, 88, 131, and 132 under 35 U.S.C. § 103(a) as being unpatentable over either Warren or Bays and Warren, and further in view of Simons.

We do not sustain the following rejections and objections:

- The objection to the amendment filed January 7, 2004 under 35 U.S.C. § 132 for introducing new matter.
- The rejection of claims 29-175, 183-185, 211-241, 245-247, 274, 275, 284, 285, and 293-300 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

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- The rejection of claims 29-175, 183-185, 211-241, 245-247, 274, 275, 284, 285, and 293-300 under 35 U.S.C. § 112, second paragraph, as being indefinite.
- The rejection of claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194 202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, and 300 under 35 U.S.C. § 103(a) as being unpatentable over Warren.
- The rejection of claims 277, 286, 287, and 295 under 35 U.S.C. § 103(a) as being unpatentable over Bays and Warren.

In sum, we affirm the decision of the Examiner to reject claims 29-276, 278-285, 288-294, and 296-300 and reverse the decision of the Examiner to reject claims 277, 286, 287, and 295.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED-IN-PART

Vsh

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